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UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,670,444

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,670,444, which claims the animal drug product BAYTRIL® (enrofloxacin) and a method of use of BAYTRIL® (enrofloxacin), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be three years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of three years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 18, 1997 (62 Fed. Reg. 12831). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (648 - 648) + 3,686 - 273
= 3,413 days (9.35 years)

Since the regulatory review period began November 24, 1984, before the patent issued (June 2, 1987), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. 35 U.S.C. § 156(c). The testing phase of an approved product is defined as the period beginning on the date that an exemption under subsection 512(j) of the Federal Food Drug and Cosmetic Act became effective for the approved product, November 24, 1984, and ending on the date an application for the approved product was initially submitted under subsection 512(b), September 2, 1986. Since both of these dates were before the issue date of the patent, June 2, 1987, none of the testing phase has been considered. The approval phase of a product begins on the date the application for the approved product was initially submitted. For BAYTRIL®, this date was September 2, 1986, which was also before the issue date of the patent, June 2, 1987. Accordingly, since from September 2, 1986 to June 2, 1987 is 273 days, this period is subtracted from the number of days occurring in the approval phase according to the FDA determination of the length of the regulatory review period. No determination of a lack of due diligence under 35 U.S.C.

§ 156(c)(1) was made.

The three year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued (June 2, 1987) and an action described in 35 U.S.C. § 156(g)(6)(B) was taken (November 24, 1984) before the date of enactment of 35 U.S.C. § 156 with respect to the approved product (November 16, 1988, see 35 U.S.C. § 156(f)(8)). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed three years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for three years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,670,444
Granted:	June 2, 1987
Original Expiration Date[1]:	December 9, 2003
Applicant:	Klaus Grohe, et al.
Owner of Record:	Bayer Aktiengesellschaft
Title:	7-Amino-1-Cyclopropyl-4-Oxo-1,4-Dihydro-Quinoline-and Naphthyridine-3-Carboxylic Acids and Antibacterial Agents Containing These Compounds
Classification:	514/300
Product Trade Name:	BAYTRIL® (enrofloxacin)
Term Extended:	Three years
Expiration Date of Extension:	December 9, 2007

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: BAYTRIL®
FDA Docket No.: 96E-0504